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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,194	08/18/2003	Rajesh Suresh Kshirsagar	116875	1110

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT PAPER NUMBER

1616

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,194

Applicant(s)

KSHIRSAGAR ET AL.

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-16, 19 and 20 is/are pending in the application.
4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☐ Claim(s) 1-16 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) 19 and 20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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Non-Final Office Action

Claims 1-16 and 19-20 are pending. Claims 19 and 20 are withdrawn as non-elected invention. Claims 1-16 are not allowed. Acknowledgment is made of the Remarks filed on February 18, 2005.

A terminal disclaimer on copending application 10/222930 has been filed by the Applicants.

Response to Remarks

In the conclusion paragraph on page 13 of the Remarks filed on February 18, 2005, it is unclear what claims the Applicants are referring to. The Applicants request the allowance of claims 1-6, 8, 12-13, and 21-22, when there is no claim 21 or claim 22. All other claims are pending in this application. A clarification is requested.

Claim for Priority

The Examiner notes the PALM records show that this application is a CIP of 10/222,930, filed on 08/19/2002. Is this correct? If not, what is the correct priority date?

Restriction Requirement

The Applicants' traversal of the restriction requirement has been noted.

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Claims 19 and 20 are drawn to processes of making the sustained release composition of claim 1. This has been withdrawn as non-elected invention for the same reasons as set forth in our previous Office Action.

Election of Species

The Applicants' election of species Cephalexin is hereby noted.

Rejection Under 35 USC 103

The arguments were fully considered, but are not found persuasive. The Examiner respectfully disagrees with the Applicants arguments. The Applicants argue that because the cited references teach different polymers from the instant invention, the rejection should be withdrawn. Claim 1 does not recite specific polymers, therefore the rejection is maintained for the same reasons as set forth in our previous Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-3 and 5-6 of copending Application No. 09/928466 (recently allowed). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The copending application is drawn to a controlled release oral composition comprising cefuroxime axetil (which is a cephasporin antibiotic) in controlled release form.

The instant invention is different from the copending application in that the instant claims are broader than the copending application. There are no galactomannans in the copending

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application. One skilled in the art would have been motivated to add any xanthan gum or any other galactomannan (which are polysaccharides) to the copending application's invention.

The Applicants need to show the criticality of the invention.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over ARORA et al (US Pat. No. 5948440) and ZHANG et al (US Pat. No. 6083532).

ARORA et al teaches a pharmaceutical composition for controlled release of an active ingredient, said composition comprising cefaclor, cephalexin, or their pharmaceutically acceptable hydrates, salts, or esters has the active ingredient, and a mixture of hydrophilic polymers of different viscosity grades. See the entire document especially claim 1.

ZHANG et al teaches a tablet for sustained release of a drug comprising an effective amount of a drug to be released at a controlled rate and a sustained release formulation, said sustained release formulation comprising at least three different types of polymers including a pH dependent gelling polymer, a pH independent gelling polymer and an enteric polymer,

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wherein said pH independent gelling polymer comprises a xantham gums. See the entire document especially claim 2.

Instant invention differs from the prior art in claiming a broader scope of galactomannans (which may include xantham gum, guar gum, and/or locust bean gum).

It would have been obvious to one skilled in the art at the time of invention to prepare a sustained release formulation of cephalosporin antibiotic, a galactomannan, and a mixture of polymers because the prior art teaches a pharmaceutical composition for controlled release of an active ingredient, said composition comprising cefaclor, cephalexin, or their pharmaceutically acceptable hydrates, salts, or esters has the active ingredient, and a mixture of hydrophilic polymers of different viscosity grades and a tablet for sustained release of a drug comprising an effective amount of a drug to be released at a controlled rate and a sustained release formulation, said sustained release formulation comprising xantham gums, which embraces the presently claimed invention.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D
PRIMARY EXAMINER

Saturday, June 11, 2005